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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,299	03/12/2004	Gerald Horn	114309-1017	7833

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,299	HORN, GERALD	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 15, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding claim 33: In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Motivation was provided based on a disclosure that was present in any of the secondary references of Lowery, Samour and Gerstenberg. If a compound applicant is reciting is known in the art, it can reasonably be expected that motivation to use the compound will be present in the secondary references disclosing the claimed compound that is the same or nearly identical to a motivation for using that compound disclosed by applicant.

2. As to applicant's arguments regarding the limitation of "consisting essentially of phentolamine", Gluchowski renders this limitation obvious for reasons stated *supra.* As to arguments regarding the limitation "a therapeutically effective amount", in light of the indefinite scope of the term "therapeutically effective amount", the term is given its broadest reasonable interpretation. As stated in the previous Office action, Gluchowski renders the range of amount of compound recited in claim 34 obvious. Applicant discloses that this range recited in claim 34 is one of the ranges present in the disclosure for the amount of phentolamine in the claimed formulation. Thus, Gluchowski renders the limitation of a compound consisting essentially of

phentolamine in a therapeutically effective amount obvious. Applicant's further argument that Gluchowski is directed to reducing intraocular pressure, not reducing pupil size was addressed in the previous action and is not persuasive. Gluchowski renders all of the remaining limitations of claim 1 obvious and thus renders this limitation obvious as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gluchowski (U.S. Patent No. 5,252,295) in view of any one of Lowry (U.S. Patent No. 5,981,563), Samour et al (U.S. Patent No. 5,942,545) and Gerstenberg et al (U.S. Patent No. 5,236,904), each one individually.

With respect to **claim 33:** Gluchowski teaches an ophthalmic formulation, comprising: a sterile aqueous carrier in the form of saline; and a pharmaceutically active compound consisting essentially of an imidazoline in a therapeutically effective amount. (Col. 4, lines 5-8, 15-20) The limitation "to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness" constitutes functional language that is given little patentable weight herein.

Gluchowski does not teach a pharmaceutically active compound consisting essentially of phentolamine. However phentolamine is an imidazoline that is known in the art as an alpha

receptor antagonist that is used to treat sexual dysfunction by its control of vasodilation as supported by each one of Lowry, Samour et al and Gerstenberg et al. Applicant states in the Specification that alpha 1 antagonists such as phentolamine that are used to treat sexual dysfunction (interpreted herein as "those known in the art for treating sexual dysfunction") can be used as the claimed pharmaceutically active compound of the claimed invention. (Specification, Page 3, line 29 – Page 4, line 4) Therefore it would be obvious to one of ordinary skill in the art to modify the formulation of Gluchowski such that the imidazoline is phentolamine with a reasonable expectation of success, as phentolamine as an alpha 1 receptor antagonist controls the degree of iris dilation (or contraction in environments with less light), which results in control of pupil contraction.

With respect to **claim 34:** Gluchowski teaches that the active agent is present in an amount between 0.0001-1% weight by volume solvent (g/cc). Gluchowski teaches a composition having 300 ml water, therefore the active agent is present in an amount between 30-3,000 mg/cc, which overlaps the range set forth in claim 34. (Col. 4, lines 20-25, Col. 12, lines 48-50)

With respect to **claim 35:** The sterile aqueous carrier taught by Gluchowski comprises saline, which is an ophthalmic artificial tear solution. (Col. 4, lines 5-7)

With respect to **claim 36:** The formulation fairly suggested by Gluchowski meets all of the remaining claim limitations of claim 36. With respect to the limitation "the pupil is effectively reduced by 1.0 mm or more", this limitation is rendered obvious by Gluchowski because the formulation consisting essentially of phentolamine that is fairly suggested by Gluchowksi will necessarily meet this limitation by virtue of meeting all of the other claim limitations as to the

claimed formulation. The motivation to modify the formulation so as to consist essentially of phentolamine is stated *supra* with respect to claim 33.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761